NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| ORTHO BIOTECH PRODUCTS, L.P.,<br><br>Plaintiff,<br><br>v.<br><br>AMGEN INC. and AMGEN USA, INC.,<br><br>Defendants. | CIVIL NO. 05-4850 (SRC)<br><br>**OPINION** |

**CHESLER, District Judge**

This matter comes before this Court on the motion of Plaintiff Ortho Biotech Products, L.P. ("Ortho" or "Plaintiff") for a preliminary injunction [docket #3], pursuant to Federal Rule of Civil Procedure 65 against Defendant Amgen Inc. ("Amgen" or "Defendant"). Between June 12, 2006 and June 16, 2006, this Court conducted an evidentiary hearing on the motion. After closing arguments on September 27, 2006, each side submitted its proposed Findings of Fact and Conclusions of Law, and filed responses to the other side's proposals. The Court has reviewed in detail those submissions, the evidence presented to the Court at the hearing, as well as oral argument of counsel, and what follows are its own Findings and Conclusions. For the reasons below, and for good cause shown, Plaintiff's motion is **DENIED.**

## I. INTRODUCTION

Plaintiff Ortho, is a New Jersey limited partnership and a subsidiary of Johnson &

Johnson. Defendant Amgen USA, a Delaware Corporation, is a wholly owned subsidiary of Defendant Amgen Inc., also a Delaware Corporation.

On October 11, 2005, Ortho filed this antitrust action challenging Amgen's multi-product discounting program with respect to red blood cell growth factor drugs and white blood cell growth factor drugs, set out in the Amgen Portfolio Contract ("APC") 2006. Ortho alleges that Amgen's portfolio discount program constitutes unlawful tying under Section 1 of the Sherman Act, 15 U.S.C. § 1 (2002), and an unlawful attempt to monopolize under Section 2 of the Sherman Act. 15 U.S.C. § 2 (2002).

Ortho filed its motion for preliminary injunction the same day as its complaint. Plaintiff seeks to enjoin Defendants Amgen Inc. and Amgen USA, Inc. ("Amgen" or "Defendant") from violating Section 1 and Section 2 of the Sherman Act through Amgen's multi-product discounting program with respect to red blood cell growth factor drugs and white blood cell growth factor drugs. Amgen argues that Ortho has not met the well-established requirements for the issuance of a preliminary injunction, as they have not demonstrated irreparable injury or shown likelihood of success on the merits of their antitrust claims.

## II. FINDINGS OF FACT

### A. The Drugs

Plaintiff Ortho and Defendant Amgen both manufacture red blood cell growth factor ("RBCGF") drugs, which are used to treat anemia caused by the depletion of the human hormone erythropoietin.

Ortho's product, epoetin alfa, is sold under the brand name Procrit. Amgen developed and holds the patent to epoetin alfa, but in 1985 granted Ortho an exclusive license to develop

and distribute epoetin alfa for human indications other than anemia in patients undergoing dialysis for end stage renal disease.[1] Currently, Procrit is FDA approved to treat anemia associated with chronic kidney disease not treated with dialysis, anemia in HIV patients undergoing zidovudine treatment, and chemotherapy-induced anemia. Until 2002, Procrit was the only RBCGF on the market that was approved for indications other than dialysis induced anemia.

Subsequently, however, Amgen developed darbepoetin alfa, a synthetic form of the epoetin alfa molecule, marketed under the name Aranesp. In July 2002, Amgen gained FDA approval to market Aranesp for the treatment of chemotherapy-induced anemia, therefore directly competing with Procrit. Currently, Procrit and Aranesp are the only FDA-approved RBCGF drugs for the treatment of chemotherapy induced anemia.

Amgen also produces two white blood cell growth factor ("WBCGF") drugs— Neupogen and Neulasta. These drugs are FDA-approved to treat neutropenia, a potentially fatal, but common, side effect of chemotherapy. Neupogen and Neulasta account for the vast majority of all WBCGF drug sales, and are the only WBCGF drugs approved to treat neutropenia.[2] Ortho does not market a WBCGF drug.

Procrit and Aranesp doses are measured in different units— Procrit is dosed in International Units ("IU") and Aranesp is measured in micrograms ("mcg").

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[1]Under the licensing agreement, Amgen retained the right to market an epoetin alfa product for dialysis-induced anemia, which it does under the brand name Epogen.

[2]There is one other WBCGF drug on the market, Leukine, which is manufactured by Berlex. However, Leukine is not approved to treat neutropenia in chemotherapy patients, and accounts for a very small amount of the sales of WBCGF drugs.

B. Purchasers of WBCGF Drugs and RBCGF Drugs and Reimbursement

Plaintiffs argue that oncology clinics constitute a distinct market for the sale of WBCGF and RBCGF drugs, however, as described more fully below, the Court finds it unnecessary to address this contention. Nevertheless, given the allegations of the parties, a brief description of the different distribution channels for these drugs and reimbursement methods is warranted.

The three largest purchasers of WBCGF and RBCGF drugs are oncology clinics; retail drug stores and mail order; and hospitals. In all three channels, patients may be covered by either a private health insurance plan or a government health care program. Each payor, public or private, sets its own level of reimbursement for particular drugs, but generally reimbursement provided by private payors typically exceeds medicare reimbursement. In the case of a patient covered by private insurance, payment typically is made by a commercial insurance company or a managed care organization, at a level set by that organization.

However, according to testimony by Tom Hiriak, Senior Director of Healthcare Compliance at Ortho, and Mark Bubany, Associate Director of Strategy and Planning for New Oncology Products at Amgen, patients covered by Medicare constitute a large portion of the patients receiving these drugs— approximately 50% of the payor mix for RBCGF patients and 40% of the payor mix for WBCGF patients. (PI Tr. vol. 1, 68:24-69:3, June 12, 2006 (Hiriak Direct); PI Tr. vol. 4, 763:25-764:4, June 15, 2006 (Bubany Direct).) Because of this, the Medicare reimbursement rate for these drugs is an important factor in health care providers' decision to use one RBCGF drug over the other.

Medicare reimbursement rates are set by the Centers for Medicare and Medicaid Services, a division of the U.S. Department of Health and Human Services. Before 2005, Medicare and a

number of private insurers reimbursed clinics by setting the per-unit reimbursement rate for WBCGF and RBCGF drugs at a percentage of the drugs' published Average Wholesale Price ("AWP"). In January 2005, Medicare enacted a major change in its reimbursement policy. Medicare set the per-unit reimbursement amount for oncology clinics at 106% of the drugs published Average Sales Price ("ASP"). In January 2006, Medicare expanded this ASP reimbursement to the hospital outpatient setting.

A drugs's ASP represents the average of the actual per-unit net sale price at which the drug is sold over all distribution channels (including hospitals, pharmacies, and oncology clinics). Consequently, greater discounts or rebates will reduce ASP and therefore the level of reimbursement. Conversely, sales to customers who receive little or no discounts or rebates will raise the "average" price and, therefore, provide a higher level of reimbursement to those customers able to buy below ASP. Since ASP is, by definition, an average price, some customers will pay a net acquisition price that is above the average, and some will pay a price below that average. A byproduct, then, of the ASP system is that it is likely that some customers will be "under water"— receiving less reimbursement for a drug than their acquisition cost.

To remedy this, the Center for Medicare and Medicaid Services instituted the Competitive Acquisition Program ("CAP"). Under this program, any clinic can arrange for the procurement at ASP of drugs for its Medicare patients from a third party supplier. However, CAP requires clinics to purchase all of their physician-administered drugs from CAP, thereby eliminating all margin on drugs.

C. Early RBCGF Competition and Pricing

Prior to Aranesp's launch in late 2001, Procrit was the only RBCGF on the market that

was approved for indications other than dialysis induced anemia, and as such, held a monopoly in the non-dialysis RBCGF market. When Aranesp was launched, price competition between the two products was "fierce." (PI Tr. vol. 4, 682:25-684:12, June 15, 2006 (Bubany Direct).) Amgen marketed and priced Aranesp aggressively, and Aranesp quickly captured a share of the non-dialysis RBCGF market. By the end of 2003, Aranesp accounted for approximately 40% of the RBCGF sales to oncology clinics, and Procrit's share of the total non-dialysis RBCGF market had dropped to 68%. (Def's. Ex. 34 at OBIAMGE 00267912-16; PI Tr. vol. 4, 781:10-781:19, June 15, 2006 (Bubany Direct); PI Tr. vol. 1, 84:24-85:1, June 12, 2006 (Hiriak Direct).) During 2004, Procrit continued to lose market share in both the oncology clinic distribution channel and the total non-dialysis RBCGF market. Overall, from 2001 until the end of 2004, the total quantity of RBCGF sold significantly increased, and net prices paid for both Aranesp and Procrit fell. (PI Tr. vol. 2, 325:23-326:8, June 13, 2006 (Fisher Cross); PI Tr. vol. 5, 966:9-21, June 16, 2006 (Sibley Direct).)

As a result of this "fierce" competition, Amgen and Ortho both introduced new contract offerings, with greater discounts, to try and win customers and market shares. (PI Tr. vol. 1, 105:7-13, June 12, 2006 (Dempsey Direct); PI Tr. vol. 1, 88:5-88:9, June 12, 2006 (Hiriak Direct).) In January 2004, Ortho introduced a new oncology clinic contract, the Maximum Value Program ("MVP"). The MVP was a volume-based agreement that standardized the incentives that Ortho provided to its clinics. In response to the MVP program, in March 2004 Amgen introduced its first Amgen Portfolio Contract ("APC 2004"). APC 2004 gave oncology clinics the opportunity to receive discounts and rebates based on their total purchases of Amgen's RBCGF and WBCGF products. The larger the clinic's total purchase of RBCGF and WBCGF

drugs, the larger the clinic's rebate level.

In 2004, Medicare announced that it would be transitioning to the ASP based reimbursement rates. Under the ASP reimbursement, it became clear that Ortho and Procrit would have an advantage in terms of head-to-head cost recovery in the Medicare population. Because Procrit had FDA approval for a number of indications that Aranesp did not, Ortho made a higher proportion of its RBCGF sales to retail pharmacies, where Ortho gave very small discounts. As a result of those higher priced retail sales, Ortho could discount more aggressively to clinics with significantly less impact to its ASP than a similar discount by Amgen. Amgen referred to this advantage as a "gear ratio" advantage. (Pla's. Ex. 93 at AMG1256325, AMG1256327.)

In response to the change in Medicare reimbursement rates, as well as Ortho's "gear ratio" advantage, Amgen introduced a new portfolio contract effective January 1, 2005. Under APC 2005, all oncology clinics received off-invoice discounts, and clinics that signed APC 2005 received a supplemental rebate of at least 7.1% on all purchases of Neulasta, regardless of how much of the other Amgen products were purchased. Clinics had the opportunity to earn additional, volume-based rebates if they met a certain target level of Aranesp and WBCGF purchases on a quarterly basis. In order to qualify for these volume-based discounts, the clinic had to purchase 25% of its RBCGF drugs from Amgen, and purchase an amount of WBCGF drugs totally at least 80% of that clinics WBCGF purchases in the prior quarter. No clinic was required to purchase Aranesp in order to purchase Amgen's WBCGF products. APC 2005 was in effect from January 1, 2005 through September 30, 3005. By the third quarter of 2005, Aranesp constituted 60% of the RBCGF sales to oncology clinics, (PI Tr. vol. 2, 306:20-307:1,

June 13, 2006 (Fisher Direct)), and had a market share of 53% of the non-dialysis RBCGF market. (PI Tr. vol. 5, 923:4-7, June 16, 2005 (Daly Direct); PI Tr. vol. 5, 964:15-18, June 16, 2005 (Sibley Direct).)

D. APC 2006 and Ortho's Response

Primarily at issue in this case is APC 2006, introduced in September of 2005 and effective October 1, 2005. Amgen implemented two changes in APC 2006. First, Amgen recalibrated the discount tiers. Second, it revised the Aranesp volume target necessary to obtain portfolio rebates, raising it to a volume equivalent to 65% of the individual clinic's average quarterly RBCGF purchases during the first and second quarters of 2005. Clinics meeting these purchase targets recieved an additional 14-20% rebate on Neupogen and a 19-25% rebate on Neulasta. APC 2006 also reduced the minimum supplemental rebate on Neulasta from 7.1% to 4.0%. APC 2006 does not require clinics to purchase Aranesp to buy Amgen's WBCGF drugs. None of Amgen's discounts result in Amgen pricing any product below cost.

Ortho did not introduce a new contract, marketing program, or pricing structure in response to APC 2006. Ortho contends that it would be futile to introduce a new marketing program to meet Amgen's APC 2006 because given Amgen's ability to increase discounts on its monopoly products– Neulasta and Neupogen– Ortho would be engaged in a continuing downward spiral they would not win. Ortho therefore asserts that it has instead adopted a policy involving ad hoc discount arrangements where its marketing professionals believe there are niche opportunities for them to compete successfully on a price basis. Amgen contends that Ortho's decision not to respond to APC 2006 constitutes a calculated determination by Ortho that it does not wish to jeopardize its substantial profit margins across all channels of distribution by meeting

Amgen's marketing program. Amgen further contends that Ortho's motivation in failing to match Amgen's marketing initiative is the desire to have a preliminary injunction preserve its market share without having to erode its substantial profit margin by meeting Amgen in head to head competition. In view of the Court's determination that there has been no irreparable injury, the Court need not decide which factual position is correct.

E. Facts Relating to Ortho's Claim of Irreparable Harm

Ortho alleges that it has lost market share in the oncology clinic distribution channel– not that its overall profits have dropped. Indeed, the evidence suggests that overall, Ortho's sales of Procrit have remained at a steady level of $300 million per month, (PI Tr. vol. 1, 173:17-174:2, June 12, 2006 (Dempsey Cross)), and as a consequence profits have remained high. Therefore, factually, this substantially undermines Ortho's claims that their research and development budget has been so severely impacted by Amgen's conduct as to constitute irreparable harm. Moreover, since Ortho's asserted gear ratio advantage is in large part driven by the fact that Ortho has FDA approvals for indications that Amgen does not, it would appear that Ortho would continue to have substantial motivation to continue to maximize this competitive advantage to increase their lead in the pharmacy and hospital distribution channels.

Ortho further claims that it has lost sales and marketing staff as a result of APC 2006. The extent to which these staff cuts are attributable to declining sales in the oncology clinic distribution channel is less than clear. Indeed, Amgen introduced evidence that Ortho's plans for staff reductions pre-dated the sales losses allegedly caused by APC 2006, and were in fact part of an overall plan to downsize Ortho's sales staff. Further, Peter Batesko, Ortho's Vice President of Finance, testified that there are no plans for any more staff cuts. (Batesko Dep. 249:12-17,

March 6, 2006.) Given that it is Plaintiff's burden to establish the threat of imminent, irreparable injury, it has failed to do so.

Ortho also claims it is being irreparably harmed by loss of goodwill among its customers. However, Ortho's own evidence indicates that in the oncology clinic distribution channel, it is the clinic's profit margin on a drug that is the driving force governing a clinic's choice between Aranesp and Procrit. (*See* Ortho's Proposed Findings of Fact at 6-7.) Customer loyalty, per se, does not appear to be a significant factor, and there is no evidence that any loss of customer relationships would be permanent given the driving factor of profitability.

F. Facts Relating to the Public Interest

The parties have submitted drastically differing evidence and tests concerning relative ASP, dosage equivalence, and cost per dose of Aranesp and Procrit. The Court need not, for purposes of this decision, resolve this conflict.

## III. CONCLUSIONS OF LAW

Ortho seeks a preliminary injunction enjoining Amgen from violating Section 1 and Section 2 of the Sherman Act through its utilization of APC 2006. The Court finds that Ortho has not demonstrated the elements required to issue a preliminary injunction, therefore, its requested relief is not warranted.

A. Standard for Awarding a Preliminary Injunction

Injunctive relief is an "extraordinary remedy, which should be granted only in limited circumstances." *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989). The Court must be convinced that the following factors favor granting preliminary relief: (1) the likelihood that the moving party will succeed on the merits; (2) the extent to which the

moving party will suffer irreparable harm without injunctive relief; (3) the extent to which the nonmoving party will suffer irreparable harm if the injunction is issued; and (4) the public interest. *See, e.g.*, *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002). The Third Circuit "has placed particular weight on the probability of irreparable harm and the likelihood of success on the merits." *Appollo Tech. Corp. v. Centrosphere Indus. Corp.*, 805 F. Supp. 1157, 1205 (D.N.J. 1992) (collecting citations). A failure to demonstrate either of these elements "must necessarily result in the denial of a preliminary injunction." *Instant Air Freight Co.*, 882 F.2d at 800 (quoting *In re Arthur Treacher's Franchisee Litigation*, 689 F.2d 1137, 1143 (3d Cir. 1982)).

B. Analysis

Because "a failure to demonstrate irreparable injury must necessarily result in the denial of a preliminary injunction," *Morton v. Beyer*, 822 F.2d 364, 371 (3d Cir. 1987), the Court finds it unnecessary to address the other requirements for an injunction, including Plaintiff's likelihood of success on the merits of its antitrust claims.

In order to demonstrate irreparable harm, the plaintiff "must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial." *Instant Air Freight Co.*, 882 F.2d at 801. An antitrust plaintiff must make the same showing of irreparable harm as any other plaintiff. *Ortho Diagnostic Sys. v. Abbott Lab., Inc.*, 822 F. Supp. 145, 150 (S.D.N.Y. 1993). Economic loss, compensable by monetary damages, does not constitute irreparable harm. *Acierno v. New Castle County*, 40 F.3d 645, 653 (3d Cir. 1994). The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, "weighs heavily against a claim of irreparable harm."

*Acierno*, 40 F.3d at 653 (citing *Sampson v. Murray*, 415 U.S. 61, 90 (1974)). Thus, "in order to warrant a preliminary injunction, the injury created by a failure to issue the requested injunction must 'be of peculiar nature, so that compensation in money cannot atone for it.'" *Id.* (citing *A.O. Smith Corp. v. F.T.C.*, 530 F.2d 515, 525 (3d Cir. 1976)). The word irreparable connotes "that which cannot be repaired, retrieved, put down again, atoned for." A party seeking a mandatory injunction– one which will alter the status quo– "bears a particularly heavy burden in demonstrating its necessity." *Punnett v. Carter*, 621 F.2d 578, 582 (3d Cir. 1980).

Ortho argues that it is suffering irreparable harm in the following ways: (1) continuing reduction in the size of its clinical sales force, (*see* Ortho Proposed Findings of Fact at 44); (2) loss of customer relationships and goodwill, (*see id.*); (3) cuts in Ortho's research and development budget and cancellation of clinical trials. (*See id.* at 21.) All of these harms flow from a shrinking market share and an alleged decrease in revenues.

Generally, lost market share and decreased revenues themselves do not constitute irreparable harm. Lost revenues are a classic economic loss, and can easily be remedied by monetary damages at the end of a trial on the merits. *See, e.g.*, *Frank's GMC Truck Ctr. v. Gen. Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988). Moreover, factually, the evidence in the record does not necessarily support Ortho's claims of a significant loss in revenue. While it is true that its market share has decreased, the overall market for RBCGF products has grown substantially. The evidence before the court suggests that Ortho's revenues and profits have remained steady, even during the introduction of Amgen's various APCs. (PI Tr. vol. 1, 173:17-174:2, June 12, 2006 (Dempsey Cross).)

It is undisputed that Ortho's market share has decreased, but a loss of market share

constitutes irreparable harm only in narrow circumstances: where the market share loss occurs in a competitive industry where consumers are brand-loyal and will likely result in a permanent loss of customers, *Novartis Consumer Health*, 290 F.3d at 596, or where the company may be rendered insolvent by continuing antitrust violations. *Beilowitz v. General Motors Corp.*, 233 F. Supp. 2d 631, 644 (D.N.J. 2002). Neither of these scenarios applies here. First, Ortho itself argues that it is economics which drives an oncology clinic's decision to use Aranesp or Procrit, not brand loyalty. (*See* Ortho's Proposed Findings of Fact at 6-7.) Moreover, Ortho retains a strong presence in the oncology clinic distribution channel, as well as the other sectors it markets to. This suggests that were Ortho to succeed in the present antitrust action, its relationships with oncology clinics could be restored. There is no evidence in the record that any loss in market share would be irreversible. Second, Ortho's parent company, Johnson and Johnson, is a large corporation with diverse holdings, that will not be rendered insolvent by the continued use of APC 2006 until a trial on the merits can be held. *See Ortho Diagnostic Sys., Inc.*, 822 F. Supp. at 151 (finding that plaintiff Ortho could survive a loss in business in part because its parent corporation is Johnson & Johnson). Therefore, given the economic positions of the parties, as well as the nature of the industry, Ortho's loss of market share does not constitute irreparable harm.

Ortho's remaining claimed harms– reduction in sales force, lost customer relationships and goodwill, and a decrease in research– all stem from this alleged loss of market share and revenue caused by the introduction of APC 2006. Given this, the Court must examine whether these harms are really imminent and irreparable, or whether they too can be remedied by a monetary award at the end of a trial on the merits.

First, Ortho argues that "as a result of diminished sales of Procrit caused by APC 2006, Ortho has lost talented sales representatives, some of whom have left on their own initiative due to the company's inability to compete with Amgen and others whom Ortho had no choice but to lay-off." (*See* Ortho Proposed Findings of Fact at 21.) The loss of these sales representatives, Ortho argues, has caused a loss of Ortho's voice in the market. (*Id.*) Amgen has presented evidence that this downsizing was not caused by Amgen's introduction of APC 2006, but was in fact part of a general plan for the downsizing of the sales forces of Ortho. (*See* Def's. Ex. 63; Def's. Ex. 76 at OBIAMGE 00028435.) The Court finds it unnecessary to resolve the factual dispute over the cause of the layoffs, because this downsizing has already been implemented and Ortho's chief financial officer testified that there are no plans for future layoffs. (*See* Batesko Dep. 249:12-17, March 6, 2006.) Given that Amgen's ongoing utilization of APC 2006 poses no threat that ongoing and continuous personnel cuts will need to be made, there is no imminent and irreparable harm of future staff cuts that could be prevented by the injunction. Moreover, even if Ortho's employee layoffs are later linked to antitrust violations by Amgen, Plaintiff has failed to show that severance payments and any costs relating to the finding and training of new employees in the future cannot be reduced to money damages.

Second, Ortho contends that it is has "already lost, and will continue to lose substantial market voice, customer relationships, and associated goodwill." (Ortho Proposed Findings of Fact at 43.) It is true that in certain contexts, particularly that of trademark or false advertising claims, loss of customer relationships and goodwill may constitute irreparable harm. *See, e.g.*, *Novartis Consumer Health*, 290 F.3d at 596; *Opticians Ass'n of Am. v. Indep. Opticians of Am.*, 920 F.2d 187 (3d Cir. 1990). However, as the Third Circuit has noted, the result in those cases

was heavily influenced by the special problem of confusion that exists in cases involving trademark infringement and trade dress claims. *Acierno*, 40 F.3d at 654. The issue of confusion is not present here, and as a result, these cases are distinguishable. Ortho also relies on *Bergen Drug v. Parke, Davis, & Co.*, 307 F.2d 725 (3d Cir. 1962), for the proposition that irreparable harm includes loss of goodwill. In *Bergen Drug*, the Third Circuit upheld the grant of a preliminary injunction preventing the defendant-supplier from terminating a long-standing relationship with plaintiff-purchaser. This case is distinguishable for a number of reasons. First, the party in that case was seeking to maintain the status quo by preventing the supplier from terminating a contract. Here, to the contrary, Ortho is seeking a mandatory preliminary injunction, which would definitively alter the status quo, and as such, is disfavored. Second, the *Bergen Drug* court found that termination of the contract could cause plaintiff to suffer a permanent loss of business. As discussed above, Ortho has not demonstrated that any loss in business it will suffer will be permanent and irreversible. Quite simply, the plaintiff in *Bergen Drug* demonstrated that without maintenance of the status quo, he would suffer irreversible losses of customer relationships. Ortho has not shown any such thing, and as such, *Bergen Drug* is factually inapposite.

Third, Ortho argues that "[b]ecause of Procrit's rapidly diminishing sales, Ortho has been forced to significantly cut back on its research and development budget and to terminate ongoing and planned clinical trials." (Ortho Proposed Findings of Fact at 21.) This does not constitute irreparable harm. Any research and development which has been stalled can surely be reinstituted were Ortho to succeed at trial. Any costs associated with the research cuts or with the reinstitution of clinical trials can be remedied with monetary damages. As the Federal Circuit

has noted, "[i]f a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief." *Eli Lilly & Co. v. American Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996). "Such a rule would convert the "extraordinary" relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits." *Id.*

Overall, the Court finds that Ortho has not established the sort of specific irreparable harm that would justify enjoining Amgen from utilizing APC 2006 until a full trial on the merits. To be sure, Ortho might be less profitable during this period then it would be had the injunction been granted, but all of Ortho's alleged injuries flow from this alleged decrease in profits. The Supreme Court has indicated that "[i]t seems clear that temporary loss of income, ultimately to be recovered, does not usually constitute irreparable harm." *Sampson v. Murray*, 415 U.S. 61, 90 (1964). In this case, it appears that any loss in profits, as well as any harm collaterally flowing from these loss of profits, can remedied by monetary damages at the end of a trial on the merits. This is especially true given that the antitrust statute provides for triple damages for any proven violations. "If the simple recitation of potential economic injuries like the loss of sales, market share and profits could signify irreparable harm, it would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances." *Sunrise Med Hhg v. Airsep Corp.*, 95 F. Supp. 2d 348, 462 (W.D. Pa. 2000). The Court is unwilling to adopt such a rule. In sum, Plaintiff has failed to allege facts which, if true, could not adequately be remedied by money damages, and as a result, this Court must deny Plaintiff's request for a preliminary injunction.

## IV. CONCLUSION

For the foregoing reasons, the Court **DENIES** Plaintiff's motion for a preliminary injunction.

/s/ Stanley R. Chesler

Stanley R. Chesler, U.S.D.J.

Dated: November 21, 2006